

One question you are likely to get is:

"How do we know if COVID-19 vaccines are safe?"

EXPLAIN:

- FDA carefully reviews all safety data from clinical trials.
- FDA authorizes emergency vaccine use only when the expected benefits outweigh potential risks.
- · ACIP reviews safety data before recommending any vaccine for use.
- FDA and CDC will continue to monitor the safety of COVID-19 vaccines to make sure even very rare side effects are identified.

For example, you can say:

"COVID-19 vaccines were tested in large clinical trials to make sure they meet safety standards. Many people were recruited to participate in these trials to see how the vaccines offer protection to people of different ages, races, and ethnicities, as well as those with different medical conditions."

"Have the vaccines been tested in people like me?"

- Individuals may be referring to their racial/ethnic group, their age group, their underlying condition or other characteristics, so it is important to ask patients probing questions about their inquiry.
- Explain to patients that a diverse mix of participants participated in the COVID-19 vaccination clinical trials and share any data you have about the percentages of people from communities of colors, differing age groups, health conditions, etc., and reiterate that no serious safety concerns were identified.

"Is it better to get natural immunity rather than immunity from vaccines?"

- Explain the potential serious risk COVID-19
 poses to them and their loved ones if
 they get the illness or spread it to others,
 adding that the disease can be serious
 even if they are not in a high-risk group.
- Explain that scientists are still learning more about the virus that causes COVID-19 and there have been some instances of reinfection for individuals that have already had the disease. At this time, it is not known how long natural immunity lasts.



For example, you can say:

"Both this disease and the vaccine are new. We don't know how long protection lasts for those who get infected or those who are vaccinated. What we do know is that COVID-19 has caused very serious illness and death for a lot of people, including people who were previously healthy. If you get COVID-19, you also risk giving it to loved ones who may get sick. Getting a COVID-19 vaccine is a safer choice."

Some people may ask if the shot will hurt, make them sick, or have any side effects.

- Explain that they cannot get COVID-19 from the vaccine.
- Explain what the most common side effects from vaccination are, how severe they may be, and that they typically go away on their own within a week.
- Explain that like all medications, some people may experience short-term side effects.
- Provide a comparison if it is appropriate for the patient (for example, pain after receiving *Shingrix* for older adults who have received it).
- Make sure patients know that a fever is a potential side effect.

For example, you can say:

"These side effects are signs that your immune system is doing exactly what it is supposed to do. It is working and building up protection against disease."

You can then give more detail:

"Most people do not have serious problems after getting a vaccine. However, your arm may be sore, red, or warm to the touch. These symptoms usually go away on their own within a week. Some people report getting a headache, fever, fatigue, or body aches when getting a vaccine."

Others may be more worried about vaccine safety and longterm side effects, given that the vaccines are so new.

- Explain how FDA and CDC are continuing to monitor safety.
- Let patients know that ACIP will take action to address any potential safety problems detected.
- Compare the potential serious risk of COVID-19 illness with what is currently known about the safety of COVID-19 vaccines.

For example, you can say:

"COVID-19 vaccines are tested in large clinical trials to assess their safety and efficacy across a diverse group of people. However, it does take time and more people getting vaccinated before we learn about very rare or long-term side effects. That is why safety monitoring will continue. CDC has an independent group of experts that reviews all the safety data as they come in and provides regular safety updates. Any possible problems will be quickly investigated to determine if the issue is related to the COVID-19 vaccine and determine the best course of action. CDC encourages the public to report any adverse events to the vaccine."

Other people may wonder how many doses are needed and why.

 Explain that two shots are needed to provide the best protection against COVID-19 for both mRNA vaccines. The first shot primes the immune system, helping it recognize the virus, and the second shot strengthens the immune response. This is not uncommon, and many other vaccines require multiple doses to provide full protection.



- Explain that COVID-19 vaccines may differ in the number of doses needed and the spacing between doses, so it is important to follow up with your same healthcare provider for sequential doses.
- When applicable, explain the dosing options available in your office and encourage the patient to set up an appointment before they leave to come back for a second dose.

For example, you can say:

"Nearly all COVID-19 vaccines being studied in the United States require two shots. The first shot starts building protection, but everyone has to come back a few weeks later for the second one to get the most protection the vaccine can offer."

If the patient doesn't ask about side effects, it's important to mention them before ending the conversation. This is important for any vaccine, but it will be extra important for COVID-19 vaccine because:

- New COVID-19 vaccines are reactogenic and likely to cause side effects, especially after the 2nd dose.
- Some of the side effects may mimic COVID-19 or flu symptoms, so patients may mistakenly assume they are ill.
- Patients may worry that the vaccine gave them COVID-19—we know this is a common myth that has been circulating.

When discussing side effects, be sure to emphasize that:

- Side effects are an indication of a good immune response—so while they may be unpleasant, it means the vaccine is doing its job.
- Side effects are generally short-lived, and the patient should feel better within a day or two.
- It's very important to return for the second dose for best protection, even if they didn't feel well after receiving the first dose.

Once you've answered questions and explained side effects, encourage your patients to take at least one action, such as:

- · Scheduling the second-dose appointment right away if they got vaccinated that day
- Reading the additional information you provide them about COVID-19 vaccination if they declined vaccination.

If they decline, continue to remind them about the importance of getting a COVID-19 vaccine during future routine visits and wrap up the conversation by letting them know that you are open to continuing the discussion and answering any additional questions they may have.

The COVID-19 landscape is changing rapidly. Every week there are announcements about clinical trial data for new vaccines, and soon there will be news about the safety and efficacy of authorized vaccines once they are put into widespread use.

Find a way to keep up with the latest developments. Here are some places you can go:

- ADHS, CDC and FDA are all updating their websites frequently with the latest vaccine information.
- Many professional associations are committed to educating their members about COVID-19 vaccines and sharing the latest news. Make the time to read any emails you get from your professional association, even though you are extremely busy.
- Your state or local health department should also have the latest information. Find out if they have a way to subscribe for email updates.
- Your facility's immunization coordinator [GIVE YOUR NAME IF YOU ARE THE IMMUNIZATION COORDINATOR]



